

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ann-Kristin Karlsson et al. Art Unit : 1623
Serial No. : 09/993,669 Examiner : Leigh C. Maier
Filed : November 27, 2001 Conf. No. : 1605
Title : STERILE POWDERS, FORMULATIONS AND METHODS OF PRODUCING
THE SAME

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure, applicants submit the information contained in the Declaration of Ann-Kristin (Karlsson) Ekelund under 37 C.F.R. § 1.132 (and its Exhibits A-U11) filed with applicants' Amendment in Reply to Action of March 17, 2008 on even date herewith. In particular, applicants direct the Examiner's attention to Exhibit N (described in paragraphs 9, 12 and 13 of the Declaration) and Exhibits O, P, S, T and U1-U11 (described in paragraphs 14-17 of the Declaration). Exhibit N is the minutes of a 1996 meeting between US Food & Drug Administration personnel and AstraZeneca personnel. Exhibits O, P, S, T and U1-U11 relate to Preferid®, a budesonide-containing topical cream product. A version of the Preferid® product that was marketed in Scandinavia in the early 1980's contained ethylene oxide-treated budesonide and was marketed as "sterile". The manufacturing process included a step of treating budesonide powder with ethylene oxide, mixing the treated powder with an autoclaved water/Cetomacrogol 1000 solution to form a suspension, and mixing that suspension first with more water and then with a cream base (see Exhibit P). The resulting Preferid® cream was typically used to treat inflammation of the skin.

CERTIFICATE OF MAILING BY EFS-WEB FILING

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: September 12, 2008

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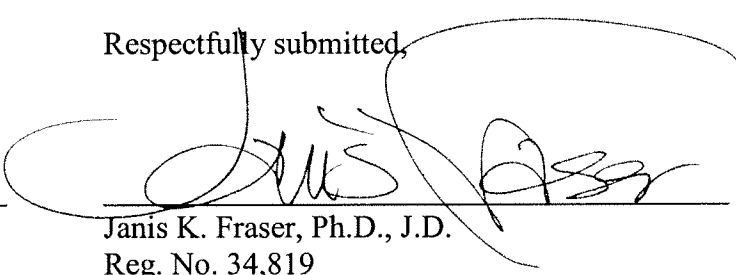
Attorney's Docket No.: 06275-160002 / D 1863-1P US

This statement is being filed after a first Office action on the merits, but before receipt of a final Office action. The fees in the amount of \$180.00 are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 06275-160002.

Respectfully submitted,

Date:

Sept. 12, 2008


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